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Mindfulness Based Cognitive Therapy for chronic tinnitus: Evaluation of benefits in a large sample of patients attending a tinnitus clinic

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Abstract

Objectives: Mindfulness-based approaches may benefit patients with chronic tinnitus, but most evidence is from small studies of non-standardized interventions, and there is little exploration of the processes of change. This study describes the impact of Mindfulness Based Cognitive Therapy (MBCT) in a 'real world' tinnitus clinic, using standardized MBCT on the largest sample of patients with chronic tinnitus to date whilst exploring predictors of change.

Design: Participants were 182 adults with chronic and distressing tinnitus who completed an eight-week MBCT group. Measures of tinnitus-related distress, psychological distress, tinnitus-acceptance and mindfulness were taken pre-intervention, post-intervention and at six-week follow-up.

Results: MBCT was associated with significant improvements on all outcome measures. Post-intervention, reliable improvements were detected in tinnitus-related distress in 50% and in psychological distress in 41.2% of patients.

Changes in mindfulness and tinnitus acceptance explained unique variance in tinnitus-related and psychological distress post-intervention.

Conclusions: MBCT was associated with significant and reliable improvements in patients with chronic, distressing tinnitus. Changes were associated with increases in tinnitus-acceptance and dispositional mindfulness. This study doubles the combined sample size of all previously published studies. Randomized controlled trials of standardized MBCT protocols are now required to test whether MBCT might offer a new and effective treatment for chronic tinnitus.

Key words: Mindfulness, MBCT, Chronic Tinnitus, Psychological Distress, Acceptance.

Introduction

In managing tinnitus, the clinical challenge is almost always one of relieving the associated distress. The use of Mindfulness Based Approaches turns the traditional ways of doing this upside down. A Cochrane review (Martinez-Devesa et al. 2010) and recent meta-analysis (Hesser et al. 2011) concluded that Cognitive Behavioural Therapy (CBT) has a positive effect on how people cope with tinnitus. CBT has been found to be more effective than other psychological treatment approaches in the care of tinnitus patients (Andersson & Lytkkens 1999). Arguably, CBT is also more effective than other tinnitus management approaches (Hesser et al. 2011). More recently, interest has grown in the development of “third wave” cognitive and behavioural therapies that place a greater emphasis on acceptance. Mindfulness Based Cognitive Therapy (MBCT) (Segal et al. 2002) is regarded as one type of “third wave” therapy.

Mindfulness

MBCT relies heavily on the use of meditation techniques as a vehicle for delivering psychotherapeutic processes particularly cognitive and behavioural ones. In contrast to most tinnitus management approaches, mindfulness involves deliberately paying attention to one’s experiences, including thoughts, emotions, body sensations, sounds and other environmental stimuli. Recognizing the tendency of the mind to focus on memories of past experiences and images of future ones, the person is invited to pay attention to their experiences in the present moment. The process also invites the person to pay attention in a non-judgmental and non-reactive way. This does not mean that the person has to refrain from having judgmental (or indeed any) thoughts, but instead they learn a new way of noticing and responding to thoughts and experiences. Mindfulness, then, becomes the practice of willingly observing and experiencing thoughts, emotions, and sensations without attempting to suppress, change, or ignore what is present. Attempts to avoid an unpleasant experience are observed, non-judgmentally and any thoughts that take form of judgment are simply observed. Mindfulness develops by noticing experience without analysis, judgment, suppression or ignoring.

This quality of mindful awareness may enable the individual to develop a new relationship with their experiences (Shapiro et al. 2006). The individual becomes more aware, but less wrapped up in thoughts, feelings and physical experiences. It is likely that a number of psychological processes are involved including exposure and the development of meta-cognitive awareness (Shapiro et al. 2006). Mindful awareness is associated with an increased acceptance of one's experiences whether pleasant, unpleasant or neutral. Acceptance has been described as the opposite of avoidance and suppression (Hayes et al. 2004), and is a process where events such as thoughts, feelings, sensations and sounds are taken in with no need to change them. Acceptance can lead to more adaptive behaviours, particularly in response to distressing experiences such as pain (Kabat-Zinn 1985).

Mindfulness-based approaches were introduced to mainstream western medicine by Jon Kabat-Zinn of the University of Massachusetts Medical Centre. His group reported that a mindfulness based treatment reduced distress and increased activity and well-being in chronic pain patients (Kabat-Zinn et al. 1982). Mindfulness based treatments have been found to improve coping and reduce relapse in patients with recurrent depression (e.g. Zautra et al. 2008) and UK guidelines now recommend MBCT in the management of depression in this context (National Institute for Health and Clinical Excellence, 2009). Mindfulness based treatments have been applied to a range of long term conditions, (e.g. Lengacher et al. 2009; Kieviet-Stijnen et al. 2008), with many studies reporting significant benefits for chronic pain patients (e.g. Nash-McFeron 2006; Gardner-Nix et al. 2008; Morone et al. 2008), a condition that shares some similarities with chronic tinnitus (Møller 2007). A meta-analysis of 39 studies of mindfulness based therapies for a range of psychiatric and medical conditions ($n = 1,140$) reported robust effect sizes: 0.63 for anxiety and 0.59 for mood symptoms in the overall sample and 0.97 and 0.95 in patients specifically with anxiety and mood disorders (Hofmann et al., 2010).

There is a growing interest in mindfulness in society and healthcare. A survey

of UK National Health Service audiology departments revealed that 27% of respondents stated that they had undertaken some training in mindfulness as part of their continuing professional development related to tinnitus (Hoare et al. 2015). Forty-eight percent of respondents had undertaken some training in CBT while only 1% had trained in Tinnitus Retraining Therapy (TRT).

Mindfulness and tinnitus

Published evidence for the utility of mindfulness-based approaches in tinnitus management is encouraging but limited. The total number of participants referred to in the published literature is 105. The current report involves that largest number of subjects to date and its addition will double the number of subjects in the literature.

Mindfulness used in a tinnitus context was first described by Sadlier et al. (2008). They delivered four, one-hour sessions of conventional CBT and education to 25 tinnitus patients, with mindfulness meditation introduced in the third session. The authors reported significant reductions in tinnitus complaint but mindfulness was only a small part of a multi-component treatment package. In conference proceedings, Mazzolli and colleagues (2010) reported improved ability to relax and control annoying tinnitus, increased periods of tinnitus absence and a change in the EEG patterns of patients after completing a mindfulness based therapy, with a modification of the ratio of alpha to delta waves in favour of the alpha rhythm. Roland et al. (2015) evaluated the impact of Mindfulness Based Stress Reduction (MBSR) on 13 patients with chronic tinnitus. They observed reductions in the severity of tinnitus and depressive symptoms. They also used fMRI and found that there was increased 'connectivity' in cortical attention networks, a potential biomarker of neural networks involved in the maintenance of tinnitus that may be modified by MBSR.

Gans et al. (2013) reported a pilot study of an eight week Mindfulness Based Tinnitus Stress Reduction intervention. This was provided to eight participants with chronic tinnitus (present for six months), previously treated with standard care, and without comorbid severe depression or anxiety. A pre- to post-

intervention design was used, and standardized questionnaires were completed before and after treatment. Measures assessed psychological state, quality of life, mindfulness, standardized and unstandardized measures of tinnitus complaint. They observed statistically significant improvements on these measures, suggesting that the intervention was beneficial, but the sample size was small and there was no follow-up evaluation.

A recent randomized controlled trial (Philippot et al. 2012) compared the effectiveness of MBCT to relaxation training in patients who had experienced tinnitus within the preceding six months and who reported significant impairment and distress relating to tinnitus. All participants received one session of psycho-education about tinnitus, followed by a two month waiting period. They were then randomized to receive six, weekly group sessions of either mindfulness or relaxation training. The authors reported that psycho-education produced statistically significant reductions in negative emotions, ruminations and psychological difficulties of living with tinnitus. At follow-up these effects were maintained or enhanced in the MBCT group but eroded in the relaxation group. The results of this study lend some support the use of MBCT in tinnitus management, but the protocol used differed from standard MBCT, and offered only six, rather than eight, sessions (Segal et al., 2002).

Kreuzer et al. (2102) report on a randomized controlled trial of 33 participants receiving a “mindfulness and body psychotherapy based intervention”, compared to a waiting list control. Over the course of two weekends (11 hours per weekend) participants were taught self-massage, breathing exercises and mindfulness meditation. There was then a seven week interval with no intervention provided to the subjects. After that there were four review meetings. The control group was similarly assessed during a waiting period of 24 weeks, before receiving treatment. The study found a significantly greater reduction in TQ scores from the start of treatment to two weeks post-treatment in the experimental group compared to the control group. The groups, however, did not differ after the final review session. Concordant effects were found for using the THI and the Beck Depression Inventory scores. The authors argued that the intervention was beneficial but these

benefits faded without continued practice. This study supports the use of Mindfulness Based Approaches in tinnitus, but again the intervention described is significantly different from generally accepted mindfulness protocols (Segal et al., 2002).

Acceptance

MBCT shares some principles and practices with Acceptance and Commitment Therapy (ACT) (Hayes 2004). Both are considered to be part of the so called "third wave" of cognitive and behavioral therapies, both involve practicing mindfulness, and both are intended to facilitate acceptance. Research has demonstrated that ACT is beneficial in reducing distress among tinnitus patients (Westin et al., 2011). A randomized controlled trial reported by Hesser et al. (2012) compared ACT to CBT for tinnitus and found them to be equally effective in alleviating tinnitus distress. Westin et al. (2011) compared ACT to Tinnitus Retraining Therapy (TRT) in a randomized controlled trial, and reported superior outcomes for tinnitus-related distress in the ACT group compared to TRT. The commonalities between ACT and MBCT lend further support to the use of mindfulness in a tinnitus clinic.

Psychological acceptance, mindfulness and experiential avoidance have been posited as key factors in tinnitus annoyance. There is growing evidence that such factors are associated with levels of tinnitus-related distress and improvements following treatment. Hesser et al. (2015) report on a cross-sectional study showing that acceptance mediates the association between loudness and severity of tinnitus. Westin et al (2008) reported a longitudinal study that showed acceptance mediated between tinnitus distress at baseline and tinnitus distress, depression, quality of life and anxiety at seven months follow-up. They describe how a tendency to avoid experience (e.g. silence, high noise levels and annoying sounds, using distraction, etc.) is typical in chronic tinnitus sufferers. Other studies describe how efforts to control tinnitus are associated with increased tinnitus-related disability (Hesser et al. 2009), and how avoidance has been associated with anxiety and tinnitus-related distress (Hesser & Andersson 2009).

A number of experimental studies report on the types of processes that may be relevant to a MBCT intervention. Hesser et al. (2009) describe how frequency of cognitive defusion behaviours and levels of acceptance after two sessions of therapy predicted outcome at six months. This group (Hesser et al., 2014) found that the tinnitus suppression subscale (i.e. experiential avoidance) mediated change across internet-delivered ACT (but not CBT) and that the activity engagement subscale mediated outcomes across both ACT and CBT. Hesser et al. (2013b) found that attempts to suppress a tinnitus-type external sound led to reduced persistence at a mental arithmetic task, but that this was attenuated by a mindfulness induction task. Taken together, these findings suggest that MBCT, an intervention aimed at reducing avoidance and suppression, and enhancing acceptance should be associated with reductions in tinnitus-related distress and potentially in psychological distress.

Aims and hypotheses

With converging evidence for Mindfulness Based Approaches in the treatment of tinnitus and the potential role played by acceptance, this study aimed to describe the effect of MBCT on a large sample of patients with chronic tinnitus, when delivered as part of routine clinical care, using standardized measures and assessing for clinically significant improvement. It also aimed to explore potential predictors and mediators of treatment outcome.

We hypothesized that:

1. MBCT would lead to a significant reduction in psychological distress as reported by numerous other studies,
2. MBCT would lead to a significant reduction in tinnitus-related distress
3. MBCT would lead to an increase in levels of dispositional mindfulness and an increase in tinnitus acceptance.
4. Changes in mindfulness and acceptance predict changes in tinnitus-related distress and change in psychological distress.

METHODS

Participants

The study was conducted by the clinical psychology team within the adult audiovestibular medicine (AVM) service of a specialist ENT Hospital based in a large urban area. Participants were adults with tinnitus who had been medically and audiotologically assessed and referred to the adult psychology service. Referral criteria for the psychology service is based on the clinical judgment of the referrer, rather than any score on a questionnaire. The psychology service accepts referrals for any patients reporting bothersome tinnitus and associated emotional distress and / or cognitive behavioural changes for which they wished to receive therapeutic intervention. A large number of patients referred reported significant anxiety and / or depression related to that experience.

Inclusion criteria:

- ☐ Chronic tinnitus (tinnitus present for more than three months) associated with psychological distress including emotional, cognitive and behavioural changes.
- ☐ Aged over 18 years.
- ☐ Agreed to take part in a group therapy, including commitment to attend all sessions of the treatment and to engage in home practice.
- ☐ Hearing sufficient to take part in group discussions.
- ☐ Sufficient grasp of English language to take part in group discussions.

Exclusion Criteria:

- ☐ Reporting active suicidal ideation or deliberate self-harm.
- ☐ Current comorbid severe mental health problems (psychosis, personality disorder, severe anxiety or mood disorders).
- ☐ Current alcohol or substance misuse.

From January 2008 to April 2014, a total of 16 MBCT groups were run as part of routine clinical practice. Over this time, a total of 820 patients with chronic tinnitus were referred to the psychology service, of which 205 were offered a place on a MBCT course.

Procedures

All patients referred to the psychology services were offered an initial appointment within three months. They were assessed by a clinical psychologist with a clinical interview and routine questionnaire measures. Those meeting inclusion criteria were given further information about MBCT including the requirements of the course (an ability and commitment to attend all sessions and to engage in regular home practice). Those interested in taking part were offered a place in the next available group, with waiting times varying from one to twelve weeks' post-assessment. Patients who did not meet inclusion criteria or who declined group MBCT were offered alternative routine care (CBT, individually delivered MBCT or referral to a more appropriate service).

The MBCT course followed the standard eight week programme (Segal et al. 2002), adapted to meet the needs of tinnitus patients. This included specific teaching on the cognitive behavioural model of tinnitus (McKenna et al., 2014) and psychoeducation about tinnitus. More time was spent during meditation practices to encourage participants to become aware of the experience of hearing and sound, including tinnitus than in most programmes and group discussions were focused on how to relate to difficult experiences of sound.

All MBCT courses were led by two clinical psychologists clinicians together and a total of three psychologists were involved, all with extensive training and expertise in delivering MBCT, CBT and in working with tinnitus. Treatment manuals for MBCT based on the standard protocol were followed carefully. To ensure treatment integrity, clinicians completed weekly briefing sessions before and after each session to ensure adherence to the manual. The clinicians also received regular supervision from a trained mindfulness practitioners accredited by the University of Bangor, to ensure continued competence in this approach.

Measures

Patients completed a battery of questionnaires at three time points: Pre-Intervention (session one), post-intervention (session eight) and follow-up (six

weeks after session eight). Basic demographic information was collected during assessment and from medical notes.

Primary clinical outcomes (Tinnitus and Psychological Distress)

The Tinnitus Questionnaire (TQ) (Hallam 1996) is a self-report questionnaire of tinnitus distress with 41 items that contribute to a total score to five subscales (emotional disturbance, intrusiveness, auditory perceptual difficulties, sleep disturbance and somatic complaints). Items are scored 0-2, with total or sub-scale scores calculated (Hallam, 1996). There is high test-retest reliability ($r = .94$) and internal consistency ($\alpha = .93$) (Hiller et al. 1994). Normative data reports on distribution of scores by quartiles (Hallam 1996) and the German version of the TQ (Hiller et al 1994) have suggested that a total score of 47 indicates a clinically significant level of tinnitus distress, however, no standard has been adopted across the literature thus far. Reliable change is probably a better representation of patient recovery than other methods of assessing change (e.g. Richards & Borglin 2011). Researchers therefore calculated the reliable change criterion for their population. The reliable change criterion (RCC) for the current population was calculated based on the Jacobson & Truax formula (1991) using the Chronbach's (α) = 0.928 and the baseline standard deviation of 14.898. This resulted in a RCC of 11.08.

The Clinical Outcomes in Routine Evaluation – Outcome Measure (CORE-OM) (Evans, et al. 2000) is a 34-item, pan-diagnostic measure of psychological distress. Items are scored on a five-point scale (0-4). Clinical scores are calculated as the mean of all items multiplied by 10 (ranging from 0 to 40). The CORE-OM has good reliability and validity in multiple settings and is acceptable to users and clinicians. Originally designed with four domains (“well-being”, “symptoms”, “functioning” and “risk”), the factor structure of the CORE-OM is such that it is best scored as two scales: “risk” and “psychological distress”. As a widely used benchmarking measure and reliable indicator of change in psychotherapy, the most useful scoring method is that in which the 28 non-risk items (CORE-NR) are scored as one scale, with the risk items scored separately and used as indicators of clinical red

flags, rather than measures of change (Lyne et al. 2006). As it is the most reliable measure of psychological distress and change, we have therefore reported the CORE-NR score (i.e. mean of the 28 non-risk items multiplied by 10). Convergent validation against other measures and clinician ratings is good (Evans, et al., 2002). An average score of 10 or more is regarded as representative of a 'clinically important' state. The reliable change criterion for the CORE is indicated by a reduction of > 5. When a subject's score moves from the clinical to the non-clinical range (i.e. from > 10 to < 10) the individual is regarded as having shown clinically significant change. Individuals showing reliable change that moves them below the clinical threshold are regarded as reliably improved and in remission.

Secondary clinical outcomes

The Mindful Attention Awareness Scale (MAAS) (Brown & Ryan 2003) is a 15-item questionnaire that measures the core characteristic of mindfulness (defined here as open or receptive awareness of and attention to what is taking place in the present). It assesses the frequency of mindful states in day-to-day life using general and situation specific items. Each item is rated on a 6 point scale from "almost always" to "almost never" (1-6). It is suitable for use with clinical populations to measure the construct of mindfulness that relates to well-being and self-awareness (Brown & Ryan 2003).

The Tinnitus Acceptance Questionnaire (TAQ) (Westin et al. 2008) is a 12-item self-report questionnaire that assesses acceptance versus experiential avoidance of tinnitus. There are two factors ("tinnitus willingness" and "activity engagement") and each subscale has good internal consistency ($\alpha = 0.70$ and $\alpha = 0.91$). The total TAQ score has a test-retest reliability of 0.74 (Westin et al., 2011).

Ethics

The hospital trust gave permission for the publication of this report as it represents an evaluation of routine clinical work.

Statistical analyses

Summaries are presented as means [SE] and n (%), as appropriate. Paired t-test analyses were used to assess the primary outcome of tinnitus-related distress (TQ) and psychological distress (CORE-NR), and secondary outcomes of dispositional mindfulness (MAAS) and tinnitus acceptance (TAQ). Comparison was made between pre-post and pre-follow-up separately. Effect sizes for the repeated measures t-tests are reported as Cohen's d and were calculated using Dunlap et al. (1996). In cases where participants completed the measures, there was less than 2% missing data on any variable. However, there was significant missing data due to attrition via non-completion of questionnaires, with data on the CORE available for 176 pre-intervention, 150 post-intervention and 82 at follow-up. Missing data was assumed to be Missing at Random (MAR) and was handled using multiple imputation (MI) using primary outcome and process variables (Ware et al. 2012). Analyses were conducted comparing the sample with complete data to those with missing data at post-treatment and follow-up. No significant differences between these groups were found in terms of pre-treatment scores or patient characteristics.

Process analyses were carried out to investigate if change from pre- to post-intervention among outcomes variables was related to the change in process variables. For these regression and correlation analyses difference scores were computed for process variables (Gollwitzer, et al. 2014) and regressed on the primary outcome variables post-intervention, while controlling for pre-intervention scores. Calculations were performed using SPSS version 24.

RESULTS

A total of 205 patients were offered MBCT with 188 completing the MBCT course (17 dropped out during treatment due to illness or competing family or work demands). Of the 188 who completed the course, 182 submitted questionnaires and were included in the analysis.

Demographic variables

Participants' mean age was 59 [11.47] years (range 83 to 27). Gender was relatively equal (43% male). All patients had chronic tinnitus (present for at

least three months) by the commencement of therapy. The average group size was 12 people (range 6 to 17).

Table 1. Effect of treatment on primary outcomes: Tinnitus and Psychological Distress (n=182)

	Pre-intervention	Post-intervention	6-week follow-up
Tinnitus distress, mean [SE]	42.52 [1.11]	30.44 [1.21]	30.72 [1.25]
Mean difference [SE]	-	12.08 [0.81]**	11.80 [0.78]**
Effect Size – Cohen's <i>d</i>	-	0.72	0.73
Reliable Improvement (reduction \geq 11.21) % (n)	-	50.0% (91)	52.8% (96)
Psychological distress, mean [SE]	15.61 [0.56]	11.80 [0.58]	12.88 [0.76]
Mean difference [SE]	-	-3.8 [0.46]**	-2.73 [0.63]**
Effect Size – Cohen's <i>d</i>	-	0.48	0.24
Reliable Improvement (reduction \geq 5) n (%)	-	41.2% (75)	36.7% (67)
Clinical Change (reduction from >10 to ≤ 10) n (%)	-	33.5% (61)	32.0% (58)
Reliable recovery (reliable improvement <i>and</i> clinically significant change) n(%)	-	28.7% (52)	21.7% (39)

*p <0.05 / **p <0.001

Primary Outcomes

Tinnitus distress (TQ)

The mean TQ score for the group was within the third quartile of scores observed in a tinnitus clinic. This can be regarded as 'moderate to severe' tinnitus distress. Paired samples t-test showed that the tinnitus distress scores decreased significantly from pre- to post-intervention: $t(181) = -14.96$,

$p < 0.001$, mean-diff = -12.08 [0.81], $d = 0.72$. Tinnitus distress scores remained significantly lower at follow-up compared to pre-intervention: $t(181) = -15.13$, $p < 0.001$, mean-diff = -11.80 [0.78], $d = 0.73$, demonstrating sustained significant improvement.

Overall there was at least some improvement shown by 83.5% of participants post-intervention, and by 86.8% of participants at follow-up. Fifty percent experienced a reliable improvement in their tinnitus distress (i.e. a reduction > 11.08) from pre- to post-intervention, and 52.8% of participants experienced a reliable improvement from pre-intervention to follow-up.

Psychological distress (CORE-NR)

Paired samples t-tests showed that psychological distress decreased significantly from pre to post-intervention: $t(181) = -8.319$, $p < 0.001$, mean-diff = -3.8 [0.46], $d = 0.48$. Similar improvement was seen from pre to follow-up: $t(181) = -4.34$, $p < 0.001$, mean-diff = -2.73 [0.63], $d = 0.24$.

From pre- to post-intervention, 75.8% of participants reported at least some improvement in psychological distress, sustained at follow-up by 67.1%. Reliable improvement post-intervention was observed in 41.2% of participants, sustained by 36.7% at follow-up. Of those who were in a clinically significant state of psychological distress (i.e. CORE-NR > 10) before the intervention, 33.5% were in a non-clinical range post-intervention and 32.0% were in a non-clinical range at follow-up. The proportion of patients demonstrating both reliable change and moving into remission (i.e. from above to below the clinical cut-off point of 10) was 28.7% of the sample post-intervention and 21.7% of the sample by follow-up.

Secondary and Process Outcomes

Mindfulness (MAAS)

Paired samples t-test showed that levels of dispositional mindfulness increased significantly from pre- to post-intervention $t(181) = 2.73$, $p < 0.05$, mean-diff = 0.19 [0.07], $d = 0.18$. This change was sustained at follow-up $t(181) = 2.19$, $p < 0.05$, mean-diff = 0.12 [0.06], $d = 0.13$.

Tinnitus acceptance (TAQ)

Paired samples t-test showed that levels of tinnitus acceptance also increased significantly from pre- to post-intervention $t(181)=10.49$, $p<0.001$, mean-diff=5.79 [0.55], $d = 0.44$. This change remained significant at follow-up $t(181)=8.18$, $p<0.001$, mean-diff=7.7 [0.95], $d = 0.4$.

Table 2. Effect of treatment on secondary outcomes: Mindfulness and tinnitus acceptance (n=182)

	Pre-intervention	Post-intervention	6-week follow-up
Mindfulness, mean [SE]	3.77 [0.08]	3.96 [0.07]	3.89 [0.08]
Mean difference [SE]	-	0.19 [0.07]*	0.12 [0.06]*
Effect Size – Cohen's <i>d</i>	-	$d=0.18$	$d=0.13$
Tinnitus acceptance, mean [SE]	34.96 [0.90]	40.46 [0.97]	42.68 [1.26]
Mean difference [SE]	-	5.79 (0.55)**	7.7 (0.95)**
Effect Size – Cohen's <i>d</i>	-	0.44	0.4

* $p < 0.05$ / ** $p < 0.01$

Process analyses

Process analyses were carried out using pre- to post-treatment change scores to investigate the hypotheses that:

- (i) change in tinnitus acceptance predicts tinnitus distress post-intervention
- (ii) change in dispositional mindfulness predicts tinnitus distress post-intervention
- (iii) change in tinnitus acceptance predicts psychological distress post-intervention
- (iv) change in dispositional mindfulness predicts psychological distress post-intervention and

- (v) change in dispositional mindfulness is associated with change in tinnitus acceptance

To examine hypothesis (i) and (ii) a stepwise multiple regression analysis was performed in which pre-intervention scores of tinnitus distress were entered to control for individual differences in the first step. In the second step, both the change in tinnitus acceptance, $b = -0.68$, $SE = 0.11$, $p < .01$, accounting for approximately 2% of the variance in tinnitus distress (squared semipartial correlation = -0.15), and the change in dispositional mindfulness, $b = -3.27$, $SE = 0.98$, $p < .01$, accounting for approximately 8% of the variance in tinnitus distress (squared semi-partial correlation = -0.284), were significant predictors of tinnitus distress post-intervention.

To examine hypothesis (iii) and (iv) a second stepwise multiple regression analysis was performed in which pre-intervention scores of psychological distress were entered to control for individual differences in the first step. Both the change in tinnitus acceptance, $b = -0.03$, $SE = 0.007$, $p < .01$, accounting for approximately 5% of the variance in tinnitus distress (squared semipartial correlation = -0.22), and the change in dispositional mindfulness, $b = -0.16$, $SE = 0.06$, $p < .05$, accounting for approximately 2% of the variance in tinnitus distress (squared semipartial correlation = -0.15), were significant independent predictors of psychological distress.

To examine hypothesis (v) a correlation analysis was conducted. Change in dispositional mindfulness was significantly and moderately correlated with change in tinnitus acceptance, $r = 0.42$, $p < .001$.

DISCUSSION

Mindfulness Based Cognitive Therapy (MBCT) led to significant reductions in tinnitus-related distress and psychological distress in patients with chronic and distressing tinnitus. Changes reflecting reliable improvement were reported by over 40% of the sample at the final week of treatment and this was maintained in the longer-term. As hypothesized, there were significant and reliable reductions in both tinnitus-related distress and global psychological

distress. These findings add to growing support for the use of Mindfulness Based Approaches and specifically a standardized MBCT intervention with chronic and distressed tinnitus patients.

The proportion of patients showing reliable improvement by the end of treatment is encouraging. Forty-four percent of participants demonstrating reliable change in tinnitus-related distress at follow-up is comparable to the results obtained using ACT, and compares favorably with TRT (e.g. Westin et al. 2011). The effect sizes for improvements in psychological well-being demonstrated in our study range from small to moderate and this is comparable to reports of the use of MBCT in other physical health conditions. (e.g. Hofmann et al. 2010). This demonstrates that a standard MBCT protocol used in a tinnitus clinic could lead to outcomes comparable to MBCT used in other areas of healthcare. MBCT may offer the potential to bring clinically meaningful changes to patients with chronic tinnitus, as evidenced by 28% of patients demonstrating clinically significant change on the measure of psychological distress. Further research is warranted using rigorous clinical trials to explore whether the benefits of MBCT could warrant its inclusion within routine clinical care.

Processes of change

This study is the first to explore how MBCT specifically might lead to changes in tinnitus-related and psychological distress. Based on the theory that tinnitus-acceptance affects distress (see Andersson & Westin 2008) and that mindfulness is an acceptance-based approach, we explored relationships between dispositional mindfulness, tinnitus acceptance and tinnitus distress. As predicted, our data clearly indicates that MBCT is associated with significant increases in tinnitus acceptance and dispositional mindfulness, assessed by using standardized measures (the TAQ and MAAS). Changes in mindfulness and tinnitus acceptance were found to be associated with changes in tinnitus-distress. This demonstrates how mindfulness may benefit tinnitus patients via the development of greater acceptance of thoughts and feelings associated with tinnitus.

We also explored what processes might account for improvements in psychological distress. Mindfulness and tinnitus acceptance were also predictors of change in psychological distress. This indicates a possible pathway of change, whereby mindfulness encourages acceptance of experiences (specifically tinnitus) which leads to a reduction in more general psychological distress. Together, these findings offer support to the theory that acceptance of tinnitus is key to both tinnitus-related and psychological distress.

Although we conducted analyses to explore the processes associated with changes in primary outcomes, the design of the study did not allow for mediation analysis and cannot provide evidence of causality. Furthermore, it is important to note that the effects on the process variables although significant, were small in magnitude. One might expect larger effects to be seen if these process variables have a great effect on outcome. MBCT is clearly associated with greater levels of tinnitus-acceptance and increased mindfulness, but the route to this remains unclear and requires further exploration using a design that would allow for full mediation analyses. The small effects of the process variables may mean that change is effected through other routes, for example, MBCT could enhance the development of a new *attitude* towards difficult experiences, such as tinnitus, in a way that is not captured by the TAQ. Alternatively, the active element of treatment might arise from the process of repeated 'exposure' to tinnitus, with extended periods of time (in class and as homework) spent sitting still in a quiet environment, with relatively little distraction from tinnitus. This warrants further investigation, possibly through further comparison of MBCT with a treatment that includes equal exposure to still and quiet situations. A small scale trial (Philippot, et al. 2012) offers initial evidence that MBCT offers more than 'exposure' as they found that the initial benefits of psycho-education were maintained or enhanced when followed by MBCT but were eroded when followed by an alternative treatment that also included an element of exposure (relaxation training).

Regardless of the specific mechanisms of change, MBCT undoubtedly offers a radically different treatment approach for tinnitus from mainstream audiology practice. Currently, most interventions for tinnitus involve attempts to avoid, suppress or ignore tinnitus using sound therapy to (partially) obscure it, recommending distraction techniques and promoting the idea of not thinking about tinnitus. Relaxation similarly fosters the idea of having to change one's internal state (by reducing stress or anxiety) in order to reduce tinnitus-related distress. These are based on very different philosophies from that underpinning acceptance and MBCT, where the patient learns how to bring attention to tinnitus (and all experiences, including stress and anxiety), without having to change anything. These significantly different view-points demonstrate why we need to further rigorously study mindfulness in tinnitus, with further randomized controlled trials.

Strengths and Limitations

This study reports on the largest sample size to date of individuals with chronic distress from tinnitus, completing a mindfulness-based treatment. It is also reflective of 'real world' treatment, as the evaluation was conducted on a sample of patients attending a tinnitus clinic, with a minimum of exclusion and inclusion criteria. The type of intervention utilized is a strength as it reflects the standard MBCT protocol that has proven effectiveness in other physical and mental health settings (Hofmann, et al. 2010).

Our results should be interpreted with acknowledgement of the limitations of conducting uncontrolled intervention studies in routine clinical settings. Most importantly, that it is not possible to assess what proportion of improvement could be accounted for by other factors, such as remission over time. This is pertinent as a community sample of tinnitus patients have been found to show reductions in tinnitus distress on standardized measures whilst awaiting treatment (Hesser et al. 2011). However, the current sample included tinnitus that had remained chronic despite previous medical or audiological intervention. It was of a severity warranting tertiary care, rather than a community sample as described by Hesser et al (2011). Finally, there was a variable waiting period of 1 to 12 weeks' pre-treatment, and baseline

measures were taken after this waiting period. These factors may somewhat ameliorate the limitations of an uncontrolled design, although we do suggest that our findings be interpreted with caution.

There are some potential sources of bias. The data was self-report, collected as part of routine clinical work, and not by independent raters. There was significant loss of data at follow-up, due to lower attendance levels at these sessions. There is potential bias that those attending follow-up are more engaged with therapy, and therefore will show more benefits of treatment. The authors believe, however, that the consistency of outcomes between post-treatment and follow-up points supports our conclusions overall. An alternative probable explanation for attrition rate to follow-up is because the follow-up sessions were not scheduled before treatment and were instead arranged with the group during week 6 or 7 of treatment. Many patients reported finding it difficult to arrange this extra time to attend, particularly if they had work or family commitments. We were also unable to accommodate long term follow-up within routine clinical practice which limits claims we can make about more sustained improvement.

Implications

Despite these limitations, present within most uncontrolled clinical studies, the results of this evaluation have important implications for the use of MBCT within the routine care of tinnitus patients. In line with previous research findings, a Mindfulness Based Approach for groups of patients with chronic and distressing tinnitus led to significant and reliable improvements in terms of tinnitus-related distress and psychological well-being, here in the largest clinical sample of this kind to date. Our findings also fit within the emerging theoretical understanding of change in distress from tinnitus, as improvements were associated with increases in mindfulness and tinnitus acceptance. These outcomes clearly warrant further investigation in the form of a randomized controlled trial with long term follow-up.

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